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10/687,327	10/16/2003	RameshBabu Boga	KCX-842 (19559)	8506

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,327	BOGA ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-82 is/are pending in the application.
- 4a) Of the above claim(s) 27-59, 82 and species in 60-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. All previously pending claims have been canceled. Claims 27-59 stand withdrawn from consideration for reasons of record, and new claims 60-82 have been added; claim 82 being directed to a non-elected
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Claims, New claim Amendments/New Grounds of Rejection

Election/Restrictions

3. Newly submitted claims 60-81 have been amended to recite new species of functional groups and therefore are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: R' and R'' have been amended to no longer require the CH₂ group as shown in Figure 5 for Alpha-naphtholbenzein and Naphthochrome Green, respectively, and as presented in original claim 5. Therefore the newly submitted claims encompass 4 new species of molecule not previously examined in the first action of the merits; the newly submitted species being structurally and functionally distinct from the originally considered species considered in the first action. Therefore, these embodiments are herein withdrawn from consideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, newly submitted claims 60-81 species defined above are herein withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

4. The amendment filed December 7, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to the Specification at page 8, line 15, inserts the phrase "source of urea". This phrase does not evidence original descriptive

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support in the instant Specification or originally presented claims. Upon consideration of the Specification, the only source of urea described is/was "urea"; no other sources evidence original descriptive support in the instant Specification. Therefore the amendment of the Specification at page 8 encompasses additional compositions that can serve as a source of urea, the source not being urea, inserts NEW Matter into the Specification. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. Claims 60-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment of the Specification at page 5, line 18 which redefines the R, R', R'' groups, provides support for the claim limitations in the new submitted claims. R'' for Michler' Hydrol has been amended to be "H" and to no longer be $(\text{CH}_3)_2\text{NC}_6\text{H}_5^-$. Claim 60 and dependent claims (61-81) recite **both** "H" and $(\text{CH}_3)_2\text{NC}_6\text{H}_5^-$; this combination of claim limitations does not evidence original descriptive support, nor does it evidence support in the newly submitted Amendment of the Table at page 5. All of the claims recite New Matter in light of the newly submitted combination of claim limitations do not evidence original descriptive support in the Table on page 5. It was noted that additional amendments were made to claim 60 to recite species of invention that also do not evidence original descriptive support in the Table on page 5 of the instant Specification.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 62 recites the limitation "alpha-naphtholbenzein and naphthochrome green" and depend from claim 60 which has been amended to no longer provide support for these two specific species of indicating agent, in light of the fact that the required CH_2 groups have been

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deleted from the previously recited R' and R" groups of claim 60. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 72 recites the limitation "fibrous material contains cellulose" in dependence upon claim 66 which recites the term "substrate"; the term "substrate" does not provide antecedent basis for the term fibrous material contains cellulose. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

9. Claims 60-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-48 of copending Application No. 10/687,270. Although the conflicting claims are not identical, they are not patentably distinct from each other because while claims 23-48 are to a species encompassed by the instantly claimed genus of kits, the copending species being referred to as a "A dispenser containing a breath testing device" (copending claims 43-45, which depends from independent claim 23), the dispenser is defined in the copending Application to be formulated into packaging, which contains a straw (copending claim 47 "cylindrical structure) and a dye treated substrate ("nanoparticles and a visual indicating agent", claims 23-27 and see [0049], [0093], and abstract). The copending species that requires the visual indicating agent to be associated with nanoparticles (copending claim 23) anticipates the instantly claimed genus of packaged materials, that are referred as kits. The instant Kits being directed to breath testing devices that comprises the visual indicating agent and a collection device, which in the co-pending application is defined to be a "cylindrical structure(claim 46-47)" and "straw (see 10/687,270

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Spec[0049]”) and in packaging materials. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 60, 62, 66, 70-76 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Bather (US Pat. 4,844,867). Bather disclose the instantly invention directed to a kit that comprises both a breath collection device (gas detection device) and a visual indicating agent which is pararosaniline.

12. The kit/device is compiled and comprises a:

Instant claim 60: breath/gas collection device (see col. 1, 15 “gas that is to be detected”; col. 3, line 28 “colorimetric gas dosimeter”);

Instant claims 60 & 62&74: an indicating agent (pararosaniline (see col. 2, line 49)

Instant claim 60 & 66: a substrate ((Figure #6 the substrate is referred to as the carrier by Bather),) referred to as cellulose base for tabs, the tabs being the component upon which the visual indicating agent is disposed

Instant claim 71-72: the cellulose being a type of fibrous material that contains cellulosic fibers (see col. 2, line 43);

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Instant claim 73: the substrate (see figure #4 “strip like carrier” is a type of substrate) being located within a passage of a carrier portion;

Instant claim 74, 75: a carrier (figure #1) that is open at least at one end (glass tube (see col. 3, lines 27-34 and Figures), “One of its ends can be opened with a cap”) and is a cylindrical structure (glass tube, see figure (see col. 3, lines 27-34 “transparent tubular glass housing”)),

Instant claim 76: carrier (figure, item #4) is substantially flattened (see additional type of carrier (see col. 2, lines 41-42: polyester foil)), the carrier having at least one open end through which the gas enters (see Figure

Instant claim 79: the visual indicating agent is applied to the substrate as a solution (see col. 1, lines 44-45 “suitably dissolved detection reagent with a pipette on fields”).

While the reference does not discuss a method of detecting ammonia but the kit/complied device composition comprises all of the claimed components of the instant composition claims referred to as a kit, and therefore anticipates the instantly claimed invention as now claimed.

13. Claims 60, 62, 66, 73 and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Scaringe et al (US Pat. 6,825,040). Scaringe et al disclose the instantly invention directed to a kit (see col. 7, lines 11-13 “transparent tube constituting a test kit with indicator paper”) for detecting a vapor/gas, the kit comprising both a breath collection device (gas collection device, tube) and a visual indicating agent which is alpha-Naphtholbenzein (see Table at col. 3-4 pH 9-11, bottom of table).

14. The kit/device is compiled and comprises a: **Instant claim 60, 62&74:** breath/gas collection device (see title, and col. 1, line 11 “test kit used in vapor”, and “indicator paper is held

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in a transparent tube like fixture”) and an indicating agent (alpha-Naphtholbenzein (see Table at col. 3-4 pH 9-11, bottom of table).

Instant claim 60 & 66: a substrate (“A pH paper is a filter paper totally impregnated with one or more of these indicator compounds”, col. 4, lines 61-62,)

Instant claim 73, 75: the substrate (see Figure 4, 5, 6, 7, 8, 9, 10 and 11 (tube cylindrical structure) being located within a passage of a carrier portion;

Instant claim 79: the visual indicating agent is applied to the substrate as a solution (see col. 5, line 30 “indicator solution”)

While the reference does not discuss a method of detecting ammonia but the kit/complied device composition comprises all of the claimed components of the instant composition claims referred to as a kit, and therefore anticipates the instantly claimed invention as now claimed.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 60,62,63-64,66-69,73-81 are rejected under 35 U.S.C. 103 as being obvious over Pan (US PG-Pub 2004/0077093) in view of Auchincloss (US Pat. 4,777,018).

Pan disclose the instantly invention directed to a kit (page 2, [0022, kit] and [0013]”breath handler and detection unit”) that comprises both a breath collection device (ammonia) and visual indicating

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agent (see Figure 2, for detection of *Helicobacter pylori* (see [0010, page 1]) for reacting with ammonia (see [0060]) for determining the presence or absence of *H.pylori* infection (see [0008, and 0010, page 1].

17. The kit/device is compiled and comprises a:

Instant claim 60: breath/gas collection device [0041, page 4] and an indicating agent (see Figure all figures, Figure 2; [0013] and [0060])

Instant claims 63-64: sensitive to ammonia to a concentration within the ranges of about 20 to 500 parts per million and about 50 to about 400 parts per million (see Figure 7, 0.1 to 100 ppm)

Instant claim 60 & 66: a substrate (polymeric material and a dye associated with the polymeric material (see page 2, [0011]) with a visual indicating agent disposed therein(also see [0057 “embed or bind the dye to the pores of the polymer”; and [0012]), the pores being from about 0.2 microns to about 9 micrometers, preferably about 2.5 microns or less (see page 5 [0051]) and the dye indicator being in a shape of beads [0056] (microns is equivalent to nanometers and therefore have a size less than about 100 nanometers

Instant claim 67-69: nanoparticles (“beads” see [0056, page 5]; microbead layer, page 4, [0043], transferred to collecting apparatus, and ammonia gas is then determined; pore size of the polymer can range from about 2.5 microns to about 1 micron)

Instant claim 73: wherein the substrate is located within a passage of a carrier portion of the breath collection device (see Figure 2, #127; figure 5, #227)

Instant claim 74:

Instant claim 74-76: a carrier portion that comprises at least one open end (tube shape, see Figure 2, 4 and 5) and is a cylindrical structure , and also comprises a carrier portion that is substantially flattened (see figure 5, #205)

Instant claim 77: wherein the carrier portion is connected to a balloon (see page 4, [0041] “the subject may exhale into a balloon and the contents of the balloon may be directly or indirectly transferred to a sensor for analysis”), wherein the direct transfer of the exhaled breath would be connected to the carrier portion for contact with the indicator portion of the ammonia detection device.

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Instant claim 78: wherein the substrate covers an end of a carrier portion of the breath collecting device (see Figure 5, where the substrate (#227) covers a portion of the carrier (#205) at near the left end of the collection device (#201))

Instant claim 79: the visual indicating agent is applied to the substrate as a solution (see page 5 [0058 “dye can be blended or mixed into the casting solution”]).

Instant claim 80-81: the concentration of the dye is within the range of about 0.001 to about 15 % wt/wt of the solution, and from about 0.005 to about 2% wt/wt (see page 5 [0058 “at least about 0.1% by weight of the dye in a solution”])

Pan (US PG-Pub 2004/0077093) teach and show a kit that comprises a breath collection device together with an indicator dye for detecting ammonia in an exhaled breath, or gas biological sample and teaches [0060] “Any dye that is sensitive to and responds to changes in the amount of ammonia that permeates the pores of the polymer may be employed. In a preferred embodiment, the dye is a pH sensitive dye”, but differs from the instantly claimed invention by failing to show the ammonia pH sensitive dye to be alpha-naphtholphthalein or pararosaniline base (also known as p-naphtholbenzein).

Auchincloss (US Pat. 4,777,018) teach alpha-naphtholphthalein or pararosaniline base (also known as p-naphtholbenzein) to be ammonia pH indicator dyes in analogous art for the purpose of detecting ammonia based upon a color change that clearly demonstrates to the operator that ammonia has been detected (see title, col. 2, lines 41-52).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the kit of Pan that comprises an ammonia indicator dye with the ammonia indicator dye of Auchincloss because both Pan and Auchincloss are directed to

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detection of ammonia with a pH sensitive color indicator and Auchincloss teaches alpha-naphtholphthalein or pararosaniline base (also known as p-naphtholbenzein) to function as indicator dyes by producing clearly demonstratable color change when that are contacted with ammonia.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of detecting ammonia with the indicator dyes for ammonia of Auchincloss (alpha-naphtholphthalein or pararosaniline base (also known as p-naphtholbenzein) in the kit of Pan, because Pan teaches that any indicator dye that will react with ammonia to produce a color change may be employed as the indicator dye in the ammonia detection kit device, and Auchincloss teaches alpha-naphtholphthalein or pararosaniline base (also known as p-naphtholbenzein) to be indicators that would successfully produce a color change when contacted with ammonia (see Auchincloss, col. 2, lines 47-52).

Pan in view of Auchincloss obviate the instantly claimed invention as now claimed.

18. Claims 60-69, 71-81, are rejected under 35 U.S.C. 103 as being obvious over Pan (US PG-Pub 2004/0077093) in view of Patel (US PG-Pub 2003/0211618).

19. See discussion of Pan above. Pan differs from the instantly claimed invention failing to show the ammonia indicator dye to be 4,4'-bis(dimethylamino)-benzhydrol (also known as Michler's), pararosaniline base, alpha-naphtholbenzein (also known as naphtholbenzein) or naphthochrome green and the device to comprise a reference zone.

20. Patel teaches indicators dye (see page 8, [0099]), specifically naphthochrome green (page 11, claim 8), Michler's (page 2, [0016]), pararosaniline base (page 5, col. 2, line 15), alpha-naphtholbenzein (also

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known as naphtholbenzein) and a reference zone (referred to as a control zone; see [0079, page 7; page 8, [0091-0093]) for incorporation into a detection device in an analogous art for the purpose of showing dyes that change color (see page 3, [0045]) when detecting gaseous vapor amines and amides (ammonia is a type of amine compound (see page 7, [0082]); see page 2, [0023]; page 4, [0056]), that are inexpensive to formulate into a detection device (see page 9, [0107]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the kit of Pan that comprises an ammonia indicator dye with the ammonia indicator dye and reference zone of Patel because both Pan and Patel are directed to detection of ammonia (amine/amide containing samples) with a pH sensitive color indicator and Patel teaches naphthochrome green, Michler's, pararosaniline base, alpha-naphtholbenzein to function as indicator dyes and are inexpensive to formulate into a detection device.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of detecting ammonia with the indicator dyes of Patel formulated into the kit of Pan, because Pan teaches that any indicator dye that will react with ammonia to produce a color change may be employed as the indicator dye in the ammonia detection kit device, and Patel teaches naphthochrome green, Michler's, pararosaniline base, alpha-naphtholbenzein to function as indicator dyes and would serve to detect ammonia by producing a color change when contacted with ammonia (an amide compound; see Patel, page 10, Table 7, "Naphthochrome green" colorless changes to Blue; see page 11, claims 8 and 22).

Pan in view of Patel obviate the instantly claimed invention as now claimed.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Various references have been cited to show indicators, detection devices for ammonia and nanoparticles of silica and alumina with a color indicator for detecting ammonia (ie. 7,052,854).

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
February 28, 2007


MARK NAVARRO
PRIMARY EXAMINER